UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,452	12/28/2001	Howard Milne Chandler	13521-002001	4341

7590 12/15/2003

Janis K. Fraser Phd J D
Fish & Richardson P C
225 Franklin Street
Boston, MA 02110-2804

EXAMINER	
CROSS, LATOYA I	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,452	Applicant(s) CHANDLER ET AL.	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on September 29, 2003 and entered as Paper No. 8. Claims 1-34 are pending. Claims 18-34 are newly added.

Withdrawal of Rejections from Previous Office Action

- All rejections from the previous Office Action are withdrawn in view of Applicants' amendment to recite that the testing element is separate from the sample collection device and that a portion of the sample collection device is received in the internal recess of the housing.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 9, 15 and 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/00712 to Chandler, hereinafter Chandler '712.

Chandler '712 teaches a test device for detecting analytes in a test sample. The device comprises a base member (housing) having a receptacle to receive an applicator. The applicator is a sample collection device. With respect to claim 1, the receptacle of the housing receives the sample collection device. The housing also receives a test strip (5), where the test strip can be in liquid communication with the sample collection device. See figure 1b, where the sample collection device (7) is inserted into the receptacle of housing (1) and in fluid contact with a test

strip (5). With respect to claims 2 and 34, the test strip (5) of Chandler '712 is separate from the sample collection device (7). At page 10, lines 17-19, Chandler '712 teaches that the specimen collection device is in fluid conducting communication with the test strip, as recited in claim 3. Chandler '712 also teaches that the specimen collection device may be a swab or dipstick, as recited in claims 4-6. With respect to claim 7, Chandler '712 teaches a first window (2, 42) for reading the test results and a second window (43) having a view of the inside of the receptacle. At page 10, line 20, the reference teaches that the test strip is preferably an immunochromatographic test strip, as recited in claim 9. With respect to claim 15, Chandler '712 teaches an opening/aperture (3) to allow additional reagents to enter the receptacle in the housing. The housing also contains an opening for allowing the sample collection device to enter the receptacle of the housing between the base and test strip, as recited in claims 27 and 33. With respect to claim 28, figure 1b of Chandler '712 shows a space allowing communication between the test strip and sample collection device. The space is partially covered with a liquid impermeable protective barrier, (cover strip), which is attached to the housing, as recited in claims 29-31. Further, Chandler '712 teaches a method for detection of analytes where the sample collection device, containing a sample suspected of having the target analyte, is introduced into the test device and allowed to contact the test strip.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Chandler '712.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler '712.

The disclosure of Chandler '712 is described in detail above. Chandler '712 fails to teach, with respect to method claims 16-26, that the insertion of the test strip occurs subsequent to the insertion of the sample collection device into the test device. Chandler '712 discloses moving the sample collection device into contact with the test strip, which is presumably already present in the test device.

The Courts have held that selection of any order of performing method steps is prima facie obvious in the absence of new or unexpected results (MPEP 2144.04). Applicants have not provided any unexpected result in inserting the test strip subsequent to insertion of the sample collection device. Chandler '712 teaches that the test strip may be test strip is movable and the components of the test device are movable with respect to one another, so they may be repositioned during the course of the testing. Chandler '712 further teaches that the test strip may be moved from position one (out of contact with the test strip) to position two (in contact with the test strip). Thus, it would have been obvious to have the test strip of Chandler '712 to contact the sample collection device subsequent to the collection device being inserted into the test device. One of ordinary skill in the art would have expected similar test results whether the test strip was inserted into the test device prior to or after the sample collection device, absent evidence to the contrary.

Therefore for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Chandler '712.

5. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler '712 in view of Kang et al

The disclosure of Chandler '712 is described in detail above. Chandler '712 differ from the instantly claimed invention, with respect to claims 10-13, in that there is no disclosure of two or more test insertable testing elements.

Kang et al teach an immunochemical assay device comprising a base member and an array over the base member having a reservoir, wicking membrane and filter zone. In figure 5 and at col. 5, lines 1-15, Kang et al teach an insertable testing elements, each having a wicking material, filter and reagents. Kang et al further teach that the reagent may be the same or different, which permits parallel tests for the same analyte or allows a plurality of different tests on the same sample.

It would have been obvious to one of ordinary skill in the art to incorporate multiple test strips into the device of Chandler '712. By using several test strips having the same reagents, a more conclusive result will be obtained since the sample will be tested for the same analyte multiple times and the user will not have to rely on one test. By using several test strips having different reagents, more efficient testing of the sample results because multiple test can be run simultaneously with one sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Chandler '712 and Kang et al.

6. Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler '712 in view of Kang et al as applied to claims 10-13 above, and further in view of US Patent 6,165,416 to Chandler, hereinafter Chandler '416.

With respect to claims 8 and 14, neither Chandler '712 nor Kang et al teaches a guaiac test strip.

Chandler '416 teaches that both immunochromatographic test strips and guaiac test strips are suitable for detecting analytes in bodily samples, especially the detection of occult blood. At col. 11, lines 3-13, the reference teaches that guaiac test strips are the most widespread technology for occult blood testing and the tests are rapid, inexpensive and easy to use.

It would have been obvious to one of ordinary skill in the art to use guaiac test strip in place of the immunochromatographic test strips of Chandler '712 because of their ability to detect analytes simply and fast.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Chandler '712, Kang et al and Chandler '416.

Response to Arguments

7. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. The Examiner is scheduled to relocated to a new office on December 17, 2003. If the Examiner cannot be reached at the number given above, Applicants should try to reach the Examiner at (571) 272-1256.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

lic
December 11, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700